Color-Urine, on AUTION 9EB multi-parameter test strip — Technical Procedure 3300
ARKRAY USA, Inc., manufacturer

Principle

Intended Use

For the determination of color in urine.
AUTION 9EB Strips are manufactured for use only in the AUTION MAX AX-4280 Urine Analyzer.

Clinical Significance

"Urochromes" are a group of pigments responsible for the color of urine. Other substances such as blood, bile, porphyrins or drugs, which do not normally appear in urine, may also contribute to its color.

Various colors may be associated with the presence of certain substances:

yellow-brown to green	bilepigments
dark brown to red	porphyrin
brown to black	hemoglobin
red	blood
blue, orange	drugs

Darker urine may indicate a more concentrated specimen whereas pale urine may be less concentrated.

Methodology

A total of 23 colors and hues are detected. The chart below shows the combination of tone and hue. Four wavelengths, R (635nm), G (565nm), B (430nm), and IR (760nm), are used to obtain the tone and hue of the urine sample. The color of the specimen is measured by comparison to four known wavelengths of light (red, violet, blue, and green), which are used to determine the color and hue of the sample. The colors are colorless, yellow, orange, brown, red, violet, blue, green and other, including light and dark of each.

Combination of Tone and Hue	
Colorless	
Light Normal Dark	Yellow
	Orange
	Brown
	Red
	Violet
	Blue
	Green
Other	

The Hue is obtained using the following measurements:

Y: Reflectance of 430nm

M: Reflectance of 565nm

C: Reflectance of 635nm

r: Reflectance of 760nm

The Tone is calculated using the following formula. The result is defined in three ranges as LIGHT, NORMAL or DARK:

$$\sqrt{\left[1+a\text{-}\frac{Y}{r}\right]^2\left[1+a\text{-}\frac{M}{r}\right]^2\left[1+a\text{-}\frac{C}{r}\right]^2}$$

Specimen Collection and Preparation

Acceptable Sample Containers

Sterile collection bottles
BD yellow top urinalysis tubes
BD tiger top urinalysis tubes with preservative.

Gray Top culture tubes are not acceptable.

Sample Collection

A clean freshly voided midstream specimen should be collected in a clean container for routine analysis, and a sterile container for UACII requests. Infant bag collections are acceptable for children ≤ 2 years of age. Other acceptable specimens include catheterized specimens, suprapubic and ostomy collections, as well as kidney or bladder collections from the operating room.

BD tiger top urinalysis preservative tubes must be filled to a level between the marked minimum and maximum lines on the tubes (7-9 mL). Under-filled or over-filled tubes are unacceptable.

For best results, BD yellow top urinalysis tubes without preservative require eight (8) mL for UA or UACII. Urine specimens with a volume < 3 mL will be diluted for microscopic analysis, if possible. Urine specimens with a volume < 1 mL may not have enough volume for microscopic analysis.

Specimens exhibiting gross hematuria cannot be tested on the AX-4280. Gross hematuria may cause incorrect results in subsequent samples.

If analysis cannot be performed within one hour after collection, immediately refrigerate (2° and 8° C) the specimen. Bring the specimen to room temperature prior to analysis. Do not centrifuge the specimen prior to analysis.

The specimen volume placed on the iQ System must be at least 3 mL. If testing on the AX-4280 module only, the minimum volume is 2 mls. If testing on the iQSeries module only, the minimum volume is 2 mL.

Sample Stability and Handling

1. Urine collected without preservative at room temperature must be delivered to the lab within 1 hour of collection.
2. Urine collected without preservative and immediately placed on ice must be delivered within 4 hours of collection.
3. Urine collected in BD urinalysis preservative tubes will be accepted up to 48 hours after collection.

All specimens should be handled using the principles of Universal Precautions, and must be capped tightly.

Specimens that leak are unacceptable for analysis.

Reagents

None.

Storage and Handling

Store AUTION strips between 1° and 30°C. DO NOT FREEZE. PROTECT AGAINST HEAT, LIGHT AND MOISTURE (Ambient Humidity). Each vial contains a desiccant to prevent exposure to moisture in the air (humidity). Immediately re-cap vials after removal of desired number of strips.

Precautions and Warnings

For In Vitro Diagnostic Use: Utilize standard precautions required for the handling of all laboratory reagents.

Warnings: Toxic. AUTION strips contain one or more of the following chemicals: Diazonium salt and phenol

Gloves: Avoid contact with skin and mucous membranes. Wearing of gloves, when handling blood and body fluids, is included in the Center for Disease Control's recommended universal precautions.

Equipment

This test on the AUTION 9EB strips is used with the AUTION MAX AX-4280 Urine Analyzer. The analyzer is manufactured and supplied by ARKRAY FACTORY, Inc. in Japan and distributed by Iris Diagnostics, A Division of IRIS International, Inc., Chatsworth, California.

For technical assistance, contact IRIS Customer Service Support at (800) 776-4747.

Calibration

None.

Quality Control

At least two levels of control material should be analyzed each shift. Parallel testing between the old shipment or lot number and the new shipment or lot number will be done to assure acceptable strip performance.

The following controls should be prepared and used in accordance with the package inserts. Allow controls to come to room temperature and mix well for several minutes before testing. Quality Control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T. Strip lot changes are documented on the IRIS reagent log sheet.

Quality Control Material

Control	Storage
MAS Liquid UA Abnormal Control 1	+2°C to +8°C*
MAS Liquid UA Normal Control 3	+2°C to +8°C*

*Urine controls are received and stored at 2°C to 8°C. Bottles of controls in use are stored at +2°C to +8°C and are good for 30 days.

Testing Procedure

Follow the correct testing set-up, testing and control procedures, as outlined in the AUTION MAX AX-4280 Urine Analyzer *Operating Manual.*

Standard Reporting Format

Color is reported as a color; Colorless, Yellow, Amber, Brown, Red, Violet, Blue, Green and other by the AX-4280. Results can be printed directly from the urine analyzer and/or transferred to the LIS.

Reference interval: None, Yellow

Procedural Notes

Limitations

None.

Interferences

No substances currently can cause false negative results.

No substances currently can cause false positive results.

Performance Characteristics

Method Comparison

The performance of the AUTION MAX AX-4280 was evaluated in comparison with a commercially available automated urinalysis system. Both urinalysis systems provide semi-quantitative results. Results for the individual urine samples were referred to the respective cut-off values for each system to discriminate between negative (normal) and positive (abnormal) findings. Overall agreement, sensitivity (positive agreement), and specificity (negative agreement) between the AUTION MAX AX-4280 and the comparative system are shown in the following table.

Analyte	No. of Samples	Overall Agreement (%)	Sensitivity (%)	Specificity (%)
Color	227	97.4	40.0	100.0

Precision

Analyte	Number of Replicates	Mean	Standard Deviation	Correlation of Variation (%)
Color	21	1.88*	0.01	0.51

Additional Information

For more detailed information on the X AX-4280 Urine Analyzer, refer to the AUTION MAX AX-4280 Urine Analyzer *Operating Manual*.

References

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5. Hayashi, A., et. al., *Journal of Japan Diabetes Society*, 1992; 35:819.
6. Henry, J.B., et. al., *Clinical Diagnosis and Management by Laboratory Methods*, 17th ed. Saunders, Philadelphia; 1984; 394:1441.
7. Ringsrud, K.M, and Linné, J.J. *Urinalysis and Body Fluids, A Color Text and Atlas*, Mosby-Year Book, St. Louis; 1995; 34-73.
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9. *AUTION Strips 9EB For Urine Chemistry*, package insert, issued: Dec. 2001, Rev.: Dec. 2011; supplied by ARKRAY, Inc., Kyoto, Japan.

Prepared By	Date Adopted	Supersedes Procedure #
Michael Inn	07/09/2008	Atlas 3455.T

Revision Date	Type of Revision	Revised by	Review/Annual Review Date	Reviewed By
			07/09/2008	G. Kost
			09/15/2009	G. Kost
			10/12/2010	G. Kost
			11/16/2011	G. Kost
09/25/2012	Added acceptable sample containers	M.Inn	11/20/2013	G. Kost
03/21/2015	Changed to MAS UA Control	kdagang	04/15/2015	J. Gregg